AUG 2 6 2009

K092423

510(k) SUMMARY

Contact Information: **Mary Ann Silvius**
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Date Prepared: August 6, 2009

Device Trade Name: Remel Xpect® Flu A&B

Predicate Device: Remel Xpect® Flu A&B (K031565; S&E July 17, 2003)

Device Classification: 21 CFR 866.3330: Influenza virus serological reagents.

Intended Use: Remel Xpect® Flu A&B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigens (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. Negative tests should be confirmed by cell culture.

Device Description: The Xpect® Flu A&B is a chromatographic immunoassay for the qualitative detection of influenza A and influenza B viral antigens. The test device incorporates separate membrane strips for influenza A and for influenza B. To perform the test, the patient specimen is diluted and added to the sample wells of the device. The mixture moves along the membranes by capillary action. If present, influenza A or B viral antigens in the patient sample bind anti-influenza A or B conjugated antibodies. A visible line forms as a complex of antibody-antigen-antibody coated colored particles is captured in the test region (T). Antibody coated colored particles not bound at the test line are later captured in the control region (C) containing goat anti-mouse antibody. A visible line will always appear in the control region indicating that the test is working properly. The presence of a control line combined with the absence of a visible test line is interpreted as a negative test result.

Device Comparison:

Characteristic	Remel Xpect Flu A&B Predicate	Remel Xpect Flu A&B Additional Analytical Sensitivity
Intended Use	Remel Xpect® Flu A&B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigens (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. Negative tests should be confirmed by cell culture.	Remel Xpect® Flu A&B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigens (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. Negative tests should be confirmed by cell culture.
Sample	Qualitative; Influenza A and B viral antigens with differentiation.	Qualitative; Influenza A and B viral antigens with differentiation.
Test Methodology	Immunochromatographic membrane assay	Immunochromatographic membrane assay
Specimen Type	Nasal wash, nasal swab, and throat swab specimens	Nasal wash, nasal swab, and throat swab specimens

Summary of Performance Data:

Analytical Sensitivity:

The analytical sensitivity was evaluated using 16 influenza strains; 10 influenza A and 6 influenza B. Each viral strain was quantitated and titrated until a positive endpoint was reached using the Xpect® Flu A&B test. The amount of virus at the endpoint dilution, expressed per test, was calculated as a measure of analytical sensitivity.

Influenza Strain	Type	Detection Limit
		$TCID_{50}$/ml
A/California/04/2009	A (H1N1)	4.41×10^2
A/New Caledonia/20/1999	A (H1N1)	1.63×10^2
		$CEID_{50}$/ml
A/Puerto Rico/8/34	A (H1N1)	8.9×10^3
A/Fort Monmouth/1/47	A (H1N1)	7.9×10^1
A/New Jersey/8/76	A (H1N1)	8.9×10^1
A/Hong Kong/8/68	A (H3N2)	2.8×10^1
A/Victoria/3/75	A (H3N2)	8.9×10^2
A/Port Chalmers/1/73	A (H3N2)	4.0×10^1
A/BhGoose/QH/1/05	A (H5N1)	2.0×10^4
A/Chicken/WD/98	A (H9N2)	3.16×10^3
B/Lee/40	B	7.9×10^3
B/Allen/45	B	4×10^0
B/Maryland/1/59	B	6×10^0
B/GL/1739/54	B	8.9×10^1
B/Taiwan/2/62	B	3×10^0
B/Hong Kong/5/72	B	1.58×10^2

TCID – 50% tissue culture infectious dose; CEID – 50% chicken embryo infectious dose

Although this test has been shown to detect the influenza A/California/04/2009 (H1N1) virus cultured from a positive human specimen, the performance characteristics of this device with human specimens infected with the 2009 H1N1 influenza virus have not been established. The Xpect® Flu A&B test can distinguish between influenza A and B viruses, but it does not differentiate seasonal influenza A virus from the novel influenza A (2009 H1N1) virus and the test's ability to detect human infection with the novel influenza A 2009 H1N1 virus in clinical specimens is unknown.

SPECIAL 510(k): Device Modification
OIVD Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K092423

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:
   Remel Xpect Flu A&B Test – K031565.

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use and package labeling.

3. The modification of the device consisted of expanded reactivity table to include reactivity information for 2009 H1N1 Influenza strain A/California/04/2009. This modification has not had any effect or caused any changes to the FUNDAMENTAL SCIENTIFIC TECHNOLOGY of this device.

4. **Comparison Information** (similarities and differences):

Parameter	Device Additional Reactivity Claim Remel Xpect Flu A&B	Predicate Remel Xpect Flu A&B 510(k) Number K031565
INTENDED USE	Remel Xpect® Flu A&B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigens (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. Negative tests should be confirmed by cell culture.	Same
ANALYTE	Differentiated detection of influenza A & B nucleoprotein antigens	Same
TECHNOLOGY	Lateral flow immunochromatographic membrane assay	Same
SPECIMEN TYPE	Nasal wash, nasal swab, and throat swab specimens.	Same
ANALYTICAL SENSITIVITY	Ten A strains (four H1N1, one 2009 H1N1-swine lineage, three H3N2, one H5N1, one H9N2) and six B strains.	Eight A strains (three H1N1, three H3N2, one H5N1, one H9N2) and six B strains.

5. **Design Control Activities Summary**
   a) Sponsor provided a signed statement that:

      i) All verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) The manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

b) The method used for the Risk Analysis for the Xpect Flu A&B Test was Failure Mode Effects Analysis (FEMA). This risk analysis method provides an effective way to assess the impact of the modification on the device and its components. Potential failures are identified in terms of failure modes. For each mode, the effect on the total system is then evaluated.
c) The effects of the common biological and environmental IVD device risks were addresses with labeling.
d) The risks of false positive and false negative test results as related to the risks to patients, were addressed with labeling, appropriate training for users, customer quality control and confirmation of all negative results by cell culture.

6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. I recommend the device be determined substantially equivalent to the previously cleared device.

Stefanie Shulhan
(Reviewer's Signature)

11-5-09
(Date)

Comments

revised:8/1/03

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		X	If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: **SE**

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
   There is no difference in the indications for use.

2. Explain why there is or is not a new effect or safety or effectiveness issue:
   There is no change to the indications for use and there are no new concerns of risk raised with this modification.

3. Describe the new technological characteristics:
   There has been no change to the technological characteristics of the device.

4. Explain how new characteristics could or could not affect safety or effectiveness:
   The added analytical reactivity information does not affect the safety or effectiveness of the device; limitation of test is provided in the labeling.

5. Explain how descriptive characteristics are not precise enough:
   Provided information is sufficiently descriptive.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
   There are no new types of safety or effectiveness questions raised.

7. Explain why existing scientific methods can not be used:
   The added analytical reactivity information was derived using existing scientific methods.

8. Explain what performance data is needed:
   No additional performance data are needed.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

The added analytical reactivity information does not change the performance of the device with clinical samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JAN - 4 2010

Mary Ann Silvius
Director of New Product & Business Development
Microbiology North America
Thermo Fisher Scientific
Remel Products
12076 Santa Fe Drive
Lenexa, KS 66215
Attn: Mary Ann Silvius

Re: k092423
Trade/Device Name: Remel Xpect Flu A&B Test
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class I
Product Code: GNX
Dated: August 6, 2009
Received: August 7, 2009

Dear Ms. Silvius:

This letter corrects our substantially equivalent letter of August 26, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

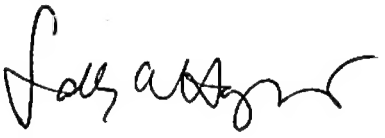
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Sally A. Hojvat, Ph.D.
Director, Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K092423

Device Name: Xpect® Flu A&B

Indications For Use: Remel Xpect® Flu A&B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigens (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections. Negative tests should be confirmed by cell culture.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K092423